

mortality rates compared to patients with no or mild MR at 30 days (12.2% vs. 6.2%,  $p=0.003$ ) and at one year (26.1% vs. 20.1%,  $p=0.046$ ). Mortality was lower in patients that were additionally treated with MitraClip® system for concomitant moderate to severe MR.

**CONCLUSIONS** Pre-existing moderate or severe mitral regurgitation is associated with an 97 % higher mortality at 30 days and 30 % higher mortality at one year as compared to patients with no or mild MR. Larger outcome studies are necessary to investigate whether additional treatment of MR in patients with concomitant moderate to severe MR will improve the prognosis in a TAVR population.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

**KEYWORDS** Mitraclip, Mitral regurgitation, TAVR

#### TCT-683

##### Early Stroke After Implantation of a Self-Expanding Transcatheter Aortic Valve Prosthesis: Experience From the CoreValve Clinical Trials

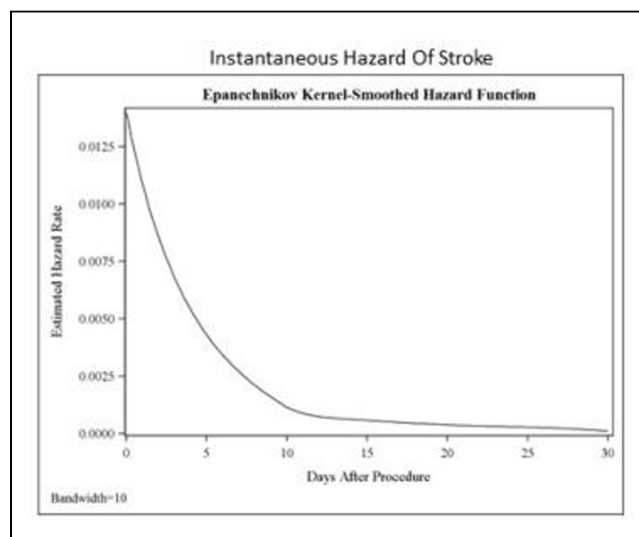
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**BACKGROUND** Risk of stroke after TAVR is a persistent concern; identification of stroke predictors would be of use in patient selection.

**METHODS** We examined the frequency and predictors of stroke among patients in the 2 CoreValve US Pivotal IDE trials and 2 Continued Access studies. Patients were followed prospectively. All patients underwent physical exam and evaluation with the NIHSS at baseline, 24 h, hospital discharge, 30 d, and 1 y postprocedure. Neurologic events lasting >24 h or with concordant imaging abnormalities were classified as strokes. Modified Rankin Scale >2 defined major stroke. All rates are K-M estimates. Instantaneous stroke hazard was modeled with the Epanechnikov kernel-smoothing function at a bandwidth = 10 points. Three predictive models were constructed using Cox Proportional Hazard functions (clinical parameters alone; clinical and imaging characteristics; clinical, imaging, and procedural characteristics).

**RESULTS** 3687 patients (3581 person-y) were included. Stroke occurred <30 d in 174 (4.8%) and <1 y in 270 (8.4%); major stroke occurred in 2.8% and 5.0%, respectively. All-cause mortality at 1 y was 45.1% for stroke patients and 63.2% for major stroke patients. Instantaneous hazard analysis showed an early inflection point at 10 d (Fig); 147 (4.1%) strokes occurred in this period. Clinical predictors of early stroke were total NIHSS >0 (HR=1.50), PVD (HR=1.44), prior TIA (HR=2.48), no prior CABG (HR=1.72), angina (HR=1.64), BMI<21 kg/m<sup>2</sup> (HR=2.14), and falls <6 mo (HR=1.73). Addition of imaging parameters did not change clinical predictors, but further addition of procedural parameters added predictors: rapid pacing during valvuloplasty (HR=9.9), total procedure time (HR=1.003), and total time delivery catheter in body (HR=1.011). Postimplant balloon dilation did not increase early stroke risk; non-iliofemoral access was of marginal significance (HR=0.668,  $P=0.058$ ).



**CONCLUSIONS** In this first prospective examination of stroke after TAVR within a series of large trials, we observed a biphasic frequency of stroke with an early hazard occurring <10 d. Clinical predictors were largely indicators of prior atherosclerotic vascular disease and frailty indices. Readily available imaging parameters contributed little, and procedural parameters reflected the complexity of the procedure. Further refinement of imaging techniques may be of help in future prediction of early stroke.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

**KEYWORDS** Stroke, TAVR, Transfemoral aortic valve replacement

#### TCT-684

##### Approach and Procedural Management in Patients Undergoing Transcatheter Aortic Valve Implantation: Results From The Written (Worldwide TAVI Experience) Survey

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**BACKGROUND** Transcatheter aortic valve implantation (TAVI) has been worldwide adopted but there are still multiple areas where consensus and evidence are lacking. Different approaches, techniques and imaging tools are actually implemented during the procedure with several differences according to local clinical practice. The objectives were to determine the real life practice related to procedural techniques used during TAVI across different centers around the world.

**METHODS** From January to May 2015, an online survey was distributed worldwide in centers performing TAVI regardless the number of procedures and valve type. There was a responsible to distribute the survey for each country or region.

**RESULTS** A total of 167 centers (including 37843 TAVI procedures) responded the questionnaire from 27 different countries in Europe,

North-America and South-America. Transfemoral approach was used in 83% of the cases followed by transapical approach (10%). Most procedures were performed in a catheterization laboratory (74%) or hybrid room (29%). An anesthesiologist assisted the transfemoral/subclavian approach procedures in 94% of centers. General anesthesia was used systematically in 43% of the centers, and 34% used general anesthesia occasionally (<25% of patients). TEE guidance was systematically used in 45% of centers. Valve type was spited half-half between balloon-expandable (Edwards valve) and self-expandable (mainly CoreValve) systems. Aortography was the most common exam used for assessing residual aortic regurgitation (90%), followed by hemodynamic evaluation (65%) and TEE (55%). Conversely, the operators relied firsts on TEE (40%) in case of discrepancies, followed by aortography (28%) and hemodynamic assessment (21%). Heparin (99.4%) was the most common anticoagulation therapy during the procedure, but activated clotting time (ACT) guidance was implemented in only 36% of the centers.

**CONCLUSIONS** This survey highlights several differences in procedural management particularly among the choice of the primary anesthetic regimen and the systematic TEE support during TAVI. Notably, discordance is present regarding the best technique to evaluate AR after TAVI, one of the most important predictors of long-term mortality.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

#### TCT-685

##### Results After Transcatheter Valve-in-Valve Implantation And Redo Aortic Valve Surgery For Failed Aortic Bioprostheses

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**BACKGROUND** Redo surgery for degeneration of biological aortic valve prostheses can be a high-risk procedure. Transcatheter aortic valve-in-valve implantation poses a less-invasive treatment alternative for these patients. We aim to present our clinical outcomes of consecutive patients after a valve-in-valve TAVI (TAV-in-SAV) as compared to a standard reoperation (SAV-in-SAV) for a failing surgical bioprosthesis in a single center setting.

**METHODS** All SAV-in-SAV and TAV-in-SAV patients from January 2001 to October 2014 were retrospectively reviewed. Patients with previous mechanical or transcatheter valves, active endocarditis and concomitant cardiac procedures were excluded. Patient characteristics, preoperative data, post-procedural complications and 30-day mortality were collected from a designated database.

**RESULTS** Of all reviewed patients, 102 fulfilled the inclusion criteria: 50 (49%) underwent a transcatheter valve-in-valve procedure, while 52 (51%) patients underwent redo-surgery. TAV-in-SAV patients were significantly older and had a higher mean logistic EuroSCORE than patients in the SAV-in-SAV group (78.1±6.7years vs. 66.2±13.1years,  $P<0.001$  and 27.4%±18.7% vs. 14.4%±10%,  $P<0.001$ , respectively). There was no significant difference between the TAV-in-SAV and SAV-in-SAV group in 30-day mortality (4% vs. 0%;  $P=0.238$ ), postoperative myocardial infarction (2% vs. 2%;  $p=0.49$ ), stroke (4% vs. 2%;  $p=0.614$ ) or dialysis (12% vs. 2%;  $p=0.057$ ). Postoperative pacemaker implantation and chest tube output were higher in the SAV-in-SAV group compared to the TAV-in-SAV group (21% vs. 6%,  $P=0.042$  and  $0.9\pm1.0l$  vs.  $0.6\pm0.9l$ ,  $P=0.047$ , respectively). Postoperative gradients were significantly higher in the TAV-in-SAV group ( $18.6\pm8.7mmHg$  vs.  $13.8\pm5.4mmHg$ ;  $p=0.008$ ).

**CONCLUSIONS** Our study shows, irrespective of different baseline comorbidities, a low 30-day mortality as well as low postoperative myocardial infarction and stroke rates in patients with failed aortic bioprostheses treated either by surgical redo or transcatheter intervention. The rate of dialysis in the TAV-in-SAV group as well as the high post-operative pacemaker rate in the SAV-in-SAV group will require further evaluation. Nonetheless, older patients or patients with a high surgical risk may benefit from the transcatheter valve-in-valve procedure.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

**KEYWORDS** Surgical aortic valve replacement, Transcatheter aortic valve replacement, Valve-in-valve

#### TCT-686

##### Impact of Aortic Valve Type on Cerebral Ischemic Lesions in DW-MRI after TAVR

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**BACKGROUND** Subclinical cerebral ischemic lesions are detected by diffusion-weighted magnetic resonance imaging (DW-MRI) in the majority of patients after TAVR which may be associated with impaired short term neurological outcome. The impact of the TAVR device on cerebral ischemic lesions is not well defined. We aimed to analyze the incidence of cerebral ischemic lesions in a large cohort of patients undergoing TAVR with different devices.

**METHODS** Consecutive high surgical risk patients with severe aortic valve stenosis treated with TAVR underwent DW-MRI 2-4 days after the procedure. DW-MRI scans were analyzed for the occurrence, number and volume of new ischemic lesions by a blinded physician.

**RESULTS** One-hundred-fifty-two patients were enrolled, the majority received an Edwards SAPIEN 3 (ES 3) (57%), 15.2% an Edwards SAPIEN XT (ES XT), 23.2% a Direct Flow Medical (DFM), 3.3% a Lotus and 1.3% an Evolut R aortic valve. Cerebral ischemic lesions were detected in 70.4%. None of the patients was neurologically symptomatic. Cerebral lesions after TAVR were found for ES XT in 56.5%, ES 3 in 70.9%, DFM in 85.7%, Lotus in 20% and Evolute R 100% of patients, respectively, which was statistically significant in univariate analysis. Logistic regression analysis revealed valve type as the only independent predictor for new cerebral ischemic lesions ( $p=0.017$ ).

**CONCLUSIONS** Asymptomatic cerebral ischemic lesions after TAVR are observed frequently. The TAVR device type has a significant impact on the incidence of new cerebral ischemic lesions.

**CATEGORIES STRUCTURAL:** Valvular Disease: Aortic

**KEYWORDS** Embolization, TAVI

#### TCT-687

##### Cerebral protection device for transcatheter valve-in-valve procedures - the ALSTER data

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**BACKGROUND** Registries for transcatheter valve-in-valve procedures show peri procedural stroke rates of about 2%. Cerebral protection devices may reduce the stroke rate and histopathology findings are unknown.

**METHODS** Twenty-one patients were treated with implantation of TAVR prostheses into degenerated bioprostheses in the aortic ( $n=16$ ) and mitral position ( $n=5$ ), combined with a Claret Cerebral Protection System (Claret Medical, Inc., Santa Rosa, CA, USA) for cerebral protection. For TAVI in aortic position 13 Corevalve/Evolut R, 2 Portico and 1 Sapien valve were used. For bioprostheses in the mitral position Sapien/Sapien 3 prostheses were exclusively implanted. Access routes were transfemoral ( $n=14$ ), transapical ( $n=3$ ), transaxillary ( $n=2$ ) and transeptal ( $n=2$ ). Mean patient age was  $75 \pm 15$  years; mean logistic EuroSCORE was 35.7%. Clinical follow-up by a cardiologist was obtained 3 days after the intervention and at discharge (mean 9 days). In cases of suspected stroke, a neurologist was consulted. Histological analyses were performed in 7 patients by the CVPath Institute in Gaithersburg, MD (additional 3 analyses are in progress).

**RESULTS** TAVR device success rate was 77% due to high mean gradients for implantations in the aortic position. Stroke rate up to discharge was 0%. TAVI device success rate was 77% due to high mean gradients